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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,249

04/11/2005

Karin A Connors

6616-72731-15

7549

57622 7590 02/04/2009

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

02/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,249	Applicant(s) CONNORS ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 22 November 2008.
2. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments to the claims.
3. The objection of record to claim 3 is withdrawn in view of Applicants' response.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the use of the limitation "Anthocyanin 1 (ANT1)" does not define the metes and bounds of the invention. Applicants define this limitation in a vague and indefinite manner on page 7, 3rd paragraph, page 8, 2nd paragraph and page 14, 2nd paragraph. The instant limitation is not an art recognized structure. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970).

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was

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not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method of obtaining flavonoids using a plant that overexpresses “Anthocyanin 1 (ANT1)”, said plant can be mutant (instant claim 3) or transgenic (instant claim 2), for example.

Applicants describe a transcription factor that regulates the production of the isoflavone glycitein in *Lypersicon esculentum* (tomato) at SEQ ID NO: 2.

Applicants do not describe a genus of mutant plants or transformation vectors that cause the overexpression of ANT1 as defined in the instant application (pages 7, 3rd paragraph, page 8, 2nd paragraph and page 14, 2nd paragraph).

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed. A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features

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common to the members of the genus, which features constitute a substantial portion of the genus.

8. Claims 1-4 and 7 remain rejected and claims 5, 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of obtaining or isolating the anthocyanins listed in Table 2 from a tomato transformed to overexpress a polypeptide having the amino acid sequence of SEQ ID NO: 2, the anthocyanins cyanidine-3-glucoside and cyanidine-3-rutinoside from tobacco, and glycitein (an isoflavone) from tomato (Specification pages 33-34 and 36-37; specification pages 20, 31-32, 36-37 and 38), does not reasonably provide enablement for a method of obtaining any flavonoid or any isoflavone in any plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 12 June 2008. Applicant's arguments filed 12 November 2008 have been fully considered but they are not persuasive.

Applicants provide limited guidance on how to make and use ANT1 encoding nucleotides and mutant plants other than the tomato ANT1 of SEQ ID NO: 2. The instant claims are very broad directed to use of any mutant plant or isolated nucleic acid encoding an ANT1 homologue, variant and fragments thereof (page 7, 3rd paragraph of the instant specification). Applicants guidance is limited in the number and types of flavonoids that can be modified in a transgenic plant as outlined in the previous Office action (page 5). Hence, it would have required undue trial and error experimentation by

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one of skill in the art at the time of Applicants' invention to make and use the invention as broadly claimed.

Applicants argue that at the time this application was filed, it was well known in the art how to analyze flavonoids (for example, anthocyanins and isoflavones) obtained from plant tissue (see, for example, the specification at Examples 7 and 8). Applicants argue that the specification also teaches how to transform various diverse species of plants (tomato, tobacco, and *Arabidopsis*) with ANT1. Applicants argue that based on the teachings of the specification and the knowledge of one of skill in the art, it would be simply a routine matter to transform any plant species with ANT1 and obtain any flavonoid from the transformed plant. Applicants argue that solely to advance prosecution in this case, claim 1 is amended to recite "extracting a flavonoid produced by the plant" (emphasis added) (page 4, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. As stated in the previous Office action the instant claims encompass a method of using plants that overexpress ANT1, but are incapable of producing a flavonoid, and the instant specification fails to teach one of skill in the art how to make and use such plants.

Applicants argue that the specification teaches that over-expression of ANT1 results in elevated levels of anthocyanins or glycitein, whereas these compounds are undetectable (or nearly undetectable) in the corresponding wild-type plant (see, for example, paragraphs [0191] and [0195]). Applicants argue that the specification teaches that the failure to detect a particular flavonoid in a wild-type plant does not preclude its production and accumulation in the plant under the appropriate conditions (for example,

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the overexpression of ANT1). Applicants argue that the claims, as amended, include the step of "extracting a flavonoid produced by the plant" (claim 1, emphasis added).

Applicants argue that the claimed method does not encompass using ANT1 overexpressing plants that do not produce flavonoids (paragraph spanning pages 4-5 of the Remarks). These arguments are not found to be persuasive because the specification does not support Applicants' assertion that the claim(s) does not encompass using ANT1 overexpression in plants that do not produce flavonoids.

The Examiner concedes to Applicants' arguments concerning the teachings of Pater *et al* on page 5, 2nd paragraph of the Remarks.

Applicants argue that there is no indication in Mathews that the presence of flavonoids other than anthocyanins, specifically, was tested. Applicants argue that there is no teaching in Mathews that steps were taken to measure the levels of flavanones, aurones, or isoflavones, and that these flavonoids failed to be detected. Applicants argue that the specification (and not Mathews) teaches that at least one isoflavone (glycitein) is detected in ANT1 overexpressing tomato plants. Applicants argue that Table 2 in Mathews is not a complete representation of the flavonoids present in an ANT1 overexpressing tomato plant. Applicants argue that based on Mathews, one cannot draw the conclusion that "overexpression of ANT1 *failed to produce ANY flavonoid*," as suggested by the Office action (paragraph spanning pages 5-6 of the Remarks). The instant Examiner does not find the teachings of Mathews *et al* particularly relevant to the instant rejection as it appears to be substantially duplicative of the instant specification.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connors *et al* (U.S. Patent 7,034,138 B2, which claim priority to U.S. Provisional Application 60/244,685 filed on 30 October 2000). The instant reference is prior art under 35 U.S.C. 102(e).

The instant claims are directed to a *prima face* obvious use of the plant of claim 8, produced by the method of claim 7 of Connors *et al*. Connors *et al* teach that the transgenic plants of the invention can be used to produce food additives (column 14, lines 8-10) which implies isolation of a water-soluble flavonoid (column 13, line 48). Given the success of Connors *et al* to make a plant that overexpresses ANT1 compared

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to a wild-type plant, one of ordinary skill in the art would have had a reasonable expectation of success in practicing a method of isolating the anthocyanins produced therefrom.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bovy *et al* (WO 99/37794).

Bovy *et al* disclose producing transgenic tomato plants transformed with a transformation vector comprising a nucleotide encoding an ANT1 homologue and extracting the flavonoid naringenin from said transgenic tomato plant (see Front Page, claim 17 and Figure 16). Bovy *et al* disclose using a tomato plant that has been selectively bred to have said ANT1 homologue at page 22, 2nd paragraph. The maize C1 transcription factor used by Bovy *et al* meets Applicants' definition of a ANT1 homologue at page 7, 3rd paragraph, page 8, 2nd paragraph and page 14, 2nd paragraph of the instant specification. The maize C1 transcription factor comprises two fragments of instant SEQ ID NO: 2 "comprises within a larger polypeptide of which the fragment forms a part or a region" (page 14, 2nd paragraph of the instant specification), those being "KSCRLRWLNLYLRP" and "LLGNRWSLIAGRLPGRT" which are 13 and 17

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amino acids in length respectively. Hence, Bovy *et al* had previously disclosed the claim limitations.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-8 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-11 of U.S. Patent No. 7,304,207.

This rejection is repeated for the reason of record as set forth in the last Office action mailed 12 June 2008. Applicant's arguments filed 12 November 2008 have been fully considered but they are not persuasive. Applicants state that because the conflicting claims are not patentably distinct from each other. Applicants respectfully requested that this rejection be held in abeyance until the claims in this application are allowed (page 6

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of the Remarks). As the instant claims are not in condition for allowance, the rejection is maintained.

16. Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 7,034,138 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to an obvious method of using the claimed plant in view of Connors *et al* teaching that the transgenic plants of the invention can be used to produce food additives (column 14, lines 8-10) which implies isolation of a water-soluble flavonoid (column 13, line 48).

Conclusion

17. No claims are allowed.
18. This Office action is non-final in view of the new ground of rejection.
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
30 January 2009